



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/782,652

02/19/2004

Knud T. Aundal

P0011329.00

4124

27581 7590 10/03/2008
MEDTRONIC, INC.
710 MEDTRONIC PARKWAY NE
MINNEAPOLIS, MN 55432-9924

EXAMINER

PANI, JOHN

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

10/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/782,652	Applicant(s) AUNDAL ET AL.	
	Examiner JOHN PANI	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 8-14, 19-30, 34-36 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 15-18, 31-33 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/11/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I Species A (Claims 1-7, 15-18, 31-33, and 37) in the reply filed on 7/11/2008 is acknowledged.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "elastic nipple" of claim 17 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New

Art Unit: 3736

Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claim 33 is objected to because of the following informalities: In line 4 it is suggested to replace "the sensor" with --the means for sensing-- in order to maintain consistent terminology. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 4, 5, 15, 16, 18, 31-33 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 5,318,533 to Adams et al. (“Adams”).

6. Adams teaches:

In reference to Claims 1 and 31

A catheter system comprising: a catheter (200) defining an internal lumen (204); a balloon (202) mounted on the catheter, the balloon defining an internal chamber in fluid communication with the lumen; a charging mechanism/means for charging including a closed reservoir (14, 20, closed when 26 is closed), a passage (portion of 26

Art Unit: 3736

on distal side of stopcock/valve which connects to 200, see Fig. 1), and an actuator (16, 18) to charge and discharge the balloon with at least a portion of a volume of fluid contained in the closed reservoir, wherein the closed reservoir is in fluid communication with the lumen via the passage (col. 3 lines 45-49) and substantially sealed from an environment outside the catheter system (see Fig. 1); and a pressure sensor/means for sensing a pressure (28) in fluid communication (via 20, 26 etc.) with the lumen to sense a pressure of the fluid.

In reference to Claims 4 and 32

The catheter system of claims 1 and 31 (see above) further comprising a monitoring device (100) to monitor the sensed pressure.

In reference to Claims 5 and 33

The catheter system of claims 1 and 31 (see above) further comprising a sensor body (10, 24, 26) that houses the sensor/sensing means, and a catheter body (most proximal section of 200 which connects to 26) coupled to a proximal end of the catheter and the sensor body (see Figs. 1,2), the catheter body defining a channel (some channel in the connection is necessary for the device to work) for fluid communication between the lumen and the sensor, wherein the reservoir and the charging mechanism are housed in the sensor body.

In reference to Claims 15 and 16

The catheter system of claim 1 (see above) wherein the actuator includes a piston and a screw, wherein the distal end of the piston ("piston") and screw (16) are

Art Unit: 3736

movable to drive a portion of the fluid out of the reservoir and into the lumen to charge the balloon (see col. 3 lines 29-45).

In reference to Claim 18

The catheter system of claim 1 (see above) wherein the pressure sensor comprises a strain gauge (col. 6 lines 9-13).

In reference to Claim 37

A sensor body (10, 24, 26) for a balloon catheter system, the sensor body comprising: a first fitting (26) to couple the sensor body to a catheter body; a second fitting (80) to couple the sensor body to a monitor (100); a charging mechanism including a closed reservoir (14, 20, closed when 26 is closed), a passage (portion of 26 on distal side of stopcock/valve which connects to 200, see Fig. 1), and an actuator (16,18) to charge and discharge a balloon mounted on the catheter via a lumen (204) with at least a portion of a volume of fluid contained in the closed reservoir, wherein the closed reservoir is in fluid communication with the lumen via the passage (col. 3 lines 45-49) and substantially sealed from an environment outside the balloon catheter system (see Fig. 1).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams in view of US Pat. No. 4,715,378 to Pope et al. ("Pope").

Adams teaches the device of claim 1 (see above) but does not explicitly disclose that the fluid is either a liquid or a gas. Pope teaches a balloon catheter that is inflated with either gas or liquid (col. 1 lines 9-11). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the device of Adams by filling the reservoir with either gas or liquid as the type of fluid as taught by Pope because it is obvious to use a known suitable material to predictably accomplish a known desired task.

9. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams in view of US Pat. No. 5,195,957 to Tollini et al ("Tollini").

Adams teaches the device of claim 1 (see above) but does not explicitly teach a seal member disposed between the sensor and the catheter body wherein the seal member includes a deformable surface that deforms under compression upon engagement of the sensor body and the catheter body to produce a fluid seal about the channel. Adams does teach that a Luer stopcock/valve is used to attach the inflation device to the catheter (see col. 3 lines 45-50). Tollini teaches placing an O-ring on a female Luer member to engage between the shoulder and rim of the collar on the male Luer member, thereby providing a better seal (see at least Abstract). It would have been obvious to one having ordinary skill in the art at the time of the invention to have

Art Unit: 3736

modified the device of Adams by including an O-ring between male and female Luer connectors in order to provide a better seal as taught by Tollini.

10. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Adams in view of US Pat. No. 5,577,995 to Walker et al. ("Walker").

Adams teaches the device of claim 1 (see above) and teaches that the charging mechanism includes a nipple (18) wherein pushing the nipple charges the balloon (col. 3 lines 40-45), but Adams does not teach that the material is elastic. Walker teaches that rubber (which is elastic) is used to make handles to increase the comfort of the operator (col. 7 lines 29-31). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the device of Adams by making the handle rubber in order to increase operator comfort as taught by Walker.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN PANI whose telephone number is (571)270-1996. The examiner can normally be reached on Monday-Friday 7:30 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3736

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JP 9/25/08

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736